SUPPLEMENTAL REBATE AGREEMENT

1. Parties/Period of Agreement

1.1 This Supplemental Rebate Agreement ("Agreement") is dated as of this _____by and between the State of Maine Department of Health and Human Services (Department) and Company ("Pharmaceutical Manufacturer"), for labeler codes 00000 and 00000.

1.2 This Agreement is effective on and will continue in force.

The parties, in consideration of covenants, conditions, agreements and stipulations expressed in this Agreement, do agree as follows:

2. Purpose

It is the intent of this Agreement that the Department will receive a Supplemental Rebate for Medicaid population, in addition to rebates received under the Medicaid Drug Rebate Agreement, pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8), for the Manufacturer's Covered Product(s) quarterly utilization in the Maine Medicaid Program. The parties also intend for this Agreement to meet the requirements of federal law at Section 1927 of the Social Security Act (42 USC 1396r-8).

3. Definitions

3.1 Agreement means this Supplemental Rebate Agreement, including all documents attached or incorporated by reference.

3.2 Pricing definitions applicable to State Supplemental Rebate Formulas in Attachment B:

3.2.1 Average Manufacturer Price (AMP) means the Average Manufacturer Price as set forth in 42 USC 1396r-8; as such statute may be amended from time to time excluding State Supplemental Rebate Amounts.

3.2.2 Wholesale Acquisition Cost (WAC) means the Manufacturer's US Dollar wholesale acquisition price in effect on the last day of the quarter on a unit basis as published by a third party source, such as Medispan or First DataBank, for each product and represents the Manufacturer's published price for a drug product to wholesalers.

3.2.3 Guaranteed Net Price means the final fixed price of the drug assured by the Manufacturer to the Department. as the Guaranteed Net Price determines the State Supplemental Rebate for the Covered Product for the calendar quarter through the formula: **WAC** minus the CMS rebate minus the State Supplemental Rebate must

equal Guaranteed Net Price to the State by the Pharmaceutical Manufacturer for the Covered Product for the calendar quarter.

3.3 **CMS Rebate** means, with respect to the Covered Product, the quarterly payment by the Pharmaceutical Manufacturer pursuant to Pharmaceutical Manufacturer 's Medicaid Drug Rebate Agreement made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8(3)).

3.4 **CMS** means the Centers for Medicare & Medicaid Services (formerly known as the Health Care Financing Administration) of the U.S. Department of Health and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.

3.5 **Competitive Product** means any Brand Product in the Market Basket that competes with Covered Product. The Market Basket for each drug listed on Attachment A are defined as the category the drug is placed on the Maine PDL unless otherwise defined on Attachment A.

3.6 **Covered Product** means those drugs listed on Attachment A.

3.7 **CPI Rebate** means, with respect to the Covered Product, the quarterly payment by the Pharmaceutical Manufacturer pursuant to the Pharmaceutical Manufacturer's Medicaid Drug Rebate Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8(3)).

3.8 **Maximum Allowable Cost (MAC)** shall mean the lowest reimbursement rate established by the Department for the Covered Product.

3.9 **Medicaid Drug Rebate Agreement** means the agreement in place between the Pharmaceutical Manufacturer and the U.S. Secretary of Health and Human Services, pursuant to Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508). CMS is the agency within HHS having the delegated authority to operate the Medicaid Program.

3.10 **Medicaid Member** means any person enrolled in the Department Medicaid Program and eligible to receive prescription drug benefits under a fee for service arrangement.

3.11 **Preferred Drug List(PDL)** means a document listing various pharmaceutical products covered by the Department Medicaid Program for the purpose of guiding the prescribing, dispensing and acquisition of pharmaceutical products. All drugs of manufacturers with Federal rebate agreements with CMS will remain covered, although some drugs that are Non-Preferred will require Prior Authorization consistent with Section 1927 of the Social Security Act. The DUR Committee

will review drugs on a monthly or bi-monthly basis to make recommendations to the Department for drugs to be listed as Preferred or Non-Preferred on the PDL.

3.12 **State Medicaid Program** means the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. 1396, et seq., that provides reimbursement for or coverage of prescription drug products to Medicaid Members.

3.13 **State Supplemental Rebate** means an amount paid on a calendar quarter basis by the Pharmaceutical Manufacturer to the Department for covered product utilization under the Department's fee for service Medicaid program pursuant to this Agreement. The State Supplemental Rebate is in Attachment B. For the purpose of this Agreement, the designated formula be listed on Attachment B.

3.14 **Step Care** means a defined order of therapeutic choices within either the preferred or non-preferred drug list categories.

3.15 **Unit** means a single capsule, tablet, milliliter or the lowest dispensable unit of a Covered Product as published in Medispan or First DataBank or another publisher of drug pricing data.

3.16 **USC** means the United States Code. All references in this agreement to USC chapters or sections will include any successor, amended, or replacement statute.

4 Department Obligations

4.1 **Preferred Drug List**: The Department will place Covered Products in an advantaged position relative to non-preferred products regarding the Preferred Drug List status, and depending on the designated preferred tier, the Department may place Covered Products in an advantaged position relative to other preferred products (Step Therapy). Certain Preferred Drugs, including Step Therapy drugs, may be subject to prior authorization. The Department will comply with all provisions of Section 1927 (d) (42 USC 1396r 8(d))

4.2 Preferred Drug List Documentation and Publication: The Department will communicate the inclusion of Covered Product on the Preferred Drug List to the State Medicaid Program providers through the standard notification process.

4.3 **Invoicing:** The Department will invoice the Pharmaceutical Manufacturer for State Supplemental Rebates separately from CMS Rebates using the format set forth by CMS. The Department shall submit the State Supplemental Rebate invoice to the Pharmaceutical Manufacturer within sixty (60) days after the end of each calendar quarter in which the Covered Product subject to such State Supplemental Rebate was paid for by the Department. Any amended invoice

shall be submitted by the Department within fifteen (15) months after the end of the calendar quarter in which Covered Product was paid for by the Department.

4.4 Patient Information: The Department, its agents, employees and contractors will not provide to Pharmaceutical Manufacturer any patient identifiable information or protected health information ("PHI") or any other information prohibited or regulated by laws or regulations governing confidentiality of medical or other information.

4.5 Approval of Generic: If during the duration of this Agreement a generic equivalent of any Competitive Product should become available and no federal Upper Limit is established, the Department will allow Covered Product to remain on the Preferred Drug List so long as the net cost to the Department, as defined in Attachment B, is not more than the lowest reimbursement cost for a generic equivalent.

5.0 Manufacturer Obligations

5.1 State Supplemental Rebate Payment: The Pharmaceutical Manufacturer agrees to provide a State Supplemental Rebate for each of its Covered Products that is paid by the Department and dispensed to Medicaid Members by Pharmacies for each calendar quarter that Covered Products are included in the Preferred Drug List. The Pharmaceutical Manufacturer will pay to the Department the State Supplemental Rebate amount in accordance with the formula set forth in Attachment B. Nothing in this Agreement shall be construed to relieve the Pharmaceutical Manufacturer from its obligation to pay Medicaid Drug Rebates for utilization by the Department Medicaid Members. The Department shall remit the appropriate share of the State Supplemental Rebate payments made under the Agreement to CMS as required under its approved State plan.

5.2 Payment Timeframe: The Pharmaceutical Manufacturer will pay to the Department the State Supplemental Rebate amount to which the Department is entitled in accordance with the formula set forth in Attachment B, within thirty-eight (38) days after receipt of the Department's invoice.

5.3 Payment of Interest: Payments of the State Supplemental Rebates mailed more than 90 days from the date of invoice will include the payment of interest by the Pharmaceutical Manufacturer at a rate based on the average of the bond equivalent of the weekly 90-day treasury bill auction rates during such period (as described in 42 USC § 1396b(d)(5)). Interest on the Rebates payable under this Agreement begins accruing 90 calendar days from the Manufacturer's receipt of Maine's Medicaid Utilization Information, and interest will continue to accrue until the postmark date of the Manufacturer's payment.

5.4 Incomplete Submission: The Pharmaceutical Manufacturer will have no obligation to pay State Supplemental Rebate amounts for claims that are not

submitted as part of an invoice in accordance with Section 6.3 of this Agreement. The Pharmaceutical Manufacturer will notify State or its designee of any incomplete submission within thirty-eight (38) days of the Pharmaceutical Manufacturer's receipt of such submission pursuant to Section6.3.

5.5 Over/Underpayment: If either party discovers an error in the payment of State Supplemental Rebates, it will notify the other of such error. The parties will attempt to reconcile all differences regarding such payment through discussion and negotiation. Any overpayment will be deducted from subsequent State Supplemental Rebates payable under this Agreement. In the event that no subsequent State Supplemental Rebates are payable, the Department will refund any such overpayment to the Pharmaceutical Manufacturer within thirty (30) days of the parties' acknowledgement of the overpayment. The Pharmaceutical Manufacturer will remit any underpayment to the Department within thirty (30) days of the parties' acknowledgement of such underpayment.

5.6 **Discretion to Market**: Nothing in this Agreement shall be construed to prohibit the Pharmaceutical Manufacturer's from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. It is understood that the Pharmaceutical Manufacturer is liable for the payment of State Supplemental Rebates only for Covered Products (as identified by the 11-digit NDC code) distributed (directly or through the wholesale channel) to retail Pharmacies and dispensed to Medicaid Members. If the Pharmaceutical Manufacturer elects to discontinue production, marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, the Pharmaceutical Manufacturer will make every reasonable effort to notify the Department prior to such actions.

6 Dispute Resolution

6.1 In the event that in any quarter a discrepancy in calculation of that quarter's State Supplemental Rebate is noted by the Pharmaceutical Manufacturer, which the Pharmaceutical Manufacturer and Department in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the Department by the Rebate Payment Due Date.

6.2 If the Pharmaceutical Manufacturer in good faith believes the Department's calculation of the State Supplemental Rebate is erroneous, the Manufacturer shall pay the Department that portion of the State Supplemental Rebate claimed that is not disputed by the Rebate Payment Due Date.

6.3 The Department and the Pharmaceutical Manufacturer will use their best efforts to resolve the discrepancy within sixty (60) days of receipt of written notification. Either party may, at any time and at its own expense, hire a mutually agreed upon independent auditor to verify the accuracy of the Department's calculation of the State Supplemental Rebate or the Pharmaceutical Manufacturer's calculations and

payment figures. Should an audit of pharmacy records be required to resolve disputes, the Department will cooperate with the Pharmaceutical Manufacturer and provide information by zip code of pharmacy provider upon the Pharmaceutical Manufacturer's request.

6.4 The Pharmaceutical Manufacturer will pay the amount due as a result of any ascertained underpayment, plus interest as described in section 4.3 of this Agreement, by the due date of the next quarterly payment after resolution of the dispute.

7. Term and Termination

7.1 Effective Date: This Agreement may be terminated prior to the effective date listed in 1.2 upon the occurrence of either of the following:

a) **Breach.** If either party commits a material breach of this Agreement, the non-breaching party shall deliver written notice mailed by certified mail, return receipt requested, of the alleged breach to the breaching party, with an opportunity for the breaching party to cure the breach during the thirty (30) day period following delivery. Failure to cure will give the non-breaching party the right to cancel this Agreement after the thirty (30) day period by giving the breaching party final written notice of the cancellation of this Agreement.

b) Without Cause. Either party may terminate this Agreement without cause as of the end of any calendar quarter by giving the other party ninety (90) days prior written notice.

7.2 Accrued Obligations/Remedies. The expiration or termination of this Agreement will not affect any rights or obligations of the parties that have accrued prior to the effective date of such termination. The fact that either party exercises any right of termination it may have under this Agreement will not prevent such party from pursuing any other remedy it may be entitled to in law or equity. Any remedy provided herein will not be deemed an exclusive remedy unless expressly provided for as such.

7.3 Execution, Amendment and Waiver. This Agreement will be binding only upon signature by the Department This Agreement, or any provision, may be altered, amended, or waived by written amendment executed by both parties as authorized by CMS.

7.4 Amendments to Agreement. The following provisions of this Agreement may be altered by an amendment in writing signed by both parties and approved by the appropriate Department control:

a) Section 1.2 Effective Dates
b) Section 8.4 Notices
c) Attachment A (Covered Products)

d) Attachment B (Rebate Formula)

The remainder of the Agreement will not be altered in any way except by an amendment in writing signed by both parties and authorized by CMS and the appropriate Department control agencies.

8. Miscellaneous

8.1 Record Keeping and Audit. During the term of this Agreement and for a period of three (3) years thereafter, both parties to the Agreement will use reasonable efforts at all times to ensure that they maintain accurate books, files and records relevant to this Agreement. At the Pharmaceutical Manufacturer's written request, the Department will make such information available for inspection by the Pharmaceutical Manufacturer representatives or its designated auditors during regular business hours. Upon written request, each party will otherwise have the right to inspect, up to once each year, all such relevant books and records of the other party to verify compliance with the terms of this Agreement.

8.2 Indemnification. The Pharmaceutical Manufacturer will be responsible for and will indemnify and hold the Department harmless from all claims resulting from the acts or omissions of the Pharmaceutical Manufacturer_ and any of its subcontractors in its performance of this Agreement. The Department will be responsible and will indemnify and hold the Pharmaceutical Manufacturer's harmless from all claims resulting from the acts or omissions of the Department.

8.3 Confidentiality. Except as otherwise may be required to be disclosed by law and in accordance with the Rebate Agreement between the U.S. Secretary of Health and Human Services and the drug manufacturers, information disclosed by the Pharmaceutical Manufacturer's in connection with this Agreement will not be disclosed by the Department. Each party will maintain the confidentiality of all the terms and conditions of this Agreement throughout the term hereof and for a period of three (3) years thereafter.

8.4 Notices. Any notice required or permitted to be given by either party to the other will be given in person or sent by first class mail or express delivery, addressed to the other party at the address set forth below:

_____
_____
_____

8.5 Force Majeure. Noncompliance with any obligations hereunder due to force majeure, such as acts of God, laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers, and any other causes beyond the reasonable control of the parties, shall not constitute breach of contract.

8.6 Assignment. Neither party will have the right to assign this Agreement to a third party without the prior written consent of the other party, which consent will not be unreasonably withheld. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment will relieve any party of responsibility for the performance of any obligations that have accrued prior to such assignment.

8.7 No Waiver of Rights. The failure of either party to insist upon the strict observation or performance of any provision of this Agreement or to exercise any right or remedy will not impair or waiver any such right or remedy in the future. Every right and remedy given by this Agreement to the parties will be exercised from time to time as often as appropriate.

8.8 Entire Agreement. This Agreement contains the entire agreement and understanding of the parties. This Agreement (including Attachments) may not be amended or modified except upon the written agreement of both parties.

8.9 Governing Law. This Agreement is governed by the laws of the State of Maine. In the event of a lawsuit involving this Agreement, venue is proper only in Kennebec County, Maine.

8.10 Effect of Future Laws. In the event of the enactment, promulgation, rescission, modification or judicial or CMS interpretation of any law or regulation after the date hereof which would (a) materially adversely affect the manner in which either party is obligated to perform under this Agreement, (b) adversely affect for either party the net prices or State Supplemental Rebates or other terms applicable under this Agreement, or (c) have the effect of requiring the net prices or State Supplemental Rebates or other terms applicable under this Agreement to be extended or offered to any third party, each party to this Agreement will enter into good faith negotiations with the other in order to seek to agree on reasonable terms for maintaining the intent of this Agreement affected by such enactment, promulgation, etc. Agreement on any such terms shall be in the sole discretion of each party. If the parties do not agree within sixty (60) days of a party's written request for negotiations, either party may terminate this Agreement with respect to the affected Covered Products upon expiration of the sixty (60) day period, with immediate effect.

8.11 Compliance with Law. In connection with its respective obligations under this Agreement, each party will comply with all applicable federal, state and local laws and regulations, including without limitation any disclosure or consent requirements.

8.12 Authority. The Department and the Pharmaceutical Manufacturer each represent and warrant to the other that the person signing below has all requisite legal

power and authority to execute this Agreement on behalf of each party and each party will thereby be bound.

8.13 Best Price Contingency. The effectiveness of this Agreement will be contingent on the Pharmaceutical Manufacturer's Best Price and AMP not being affected by State Supplemental Rebates.

8.14 CMS Approval Contingency. The effectiveness of this Agreement will be contingent on receipt of CMS approval by the Department, as evidenced by the CMS Exemption Letter, attached hereto as Exhibit C and incorporated by reference.

IN WITNESS WHEREOF, this Agreement has been executed by the parties set forth below:

Company Name_____	State of Maine Department of Health and Human Services
_____ Signature	_____ Signature
_____ Name (Print)	_____ Name(Print)
_____ Date	_____ Date

Manufacturer Name	NDC	Product Description	Tier

State of Maine
Attachment B

Manufacturer Name	NDC	Product Description	Tier[1]	Formula[2]	Contracted GNP	COMMENTS	Contract Effective Dates

ATTACHMENT C

CMS Exemption Letter